Text of Russian Federation Priority project "Implementation of an automated system for monitoring the movement of drugs from the manufacturer to the end user to protect the public from counterfeit medicines and surgical removal from circulation of counterfeit and substandard drugs"
(Minutes of October 25, 2016, № 9)
as translated by Google Translate on February 5, 2017

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APPROVED
the presidium of the Council
the President of the Russian Federation
Strategic Development
and priority projects
(Minutes of October 25, 2016 № 9)

P A S S P O R T

Priority project "Implementation of an automated system for monitoring the movement of drugs from the manufacturer to the end user to protect the public from counterfeit medicines and surgical removal from circulation of counterfeit and substandard drugs"

1. Basic Provisions

Subject	Health		
Short name of project	Medications. Quality and safety.	Term of the beginning and end of the project	Oct. 25, 2016 – March 1, 2019
Curator	O.Yu.Golodets, Deputy Chairman of the Government of the Russian Federation		
Senior Official Meeting (SOM) *			
Functional customer	V.I.Skvortsova, Russian Federation Minister of Health		
Project Manager	I.N.Kagramanyan, First Deputy Minister of Health of the Russian Federation		
Key members of the project	Russian Federation Ministry of Health The Federal Service on oversight in Healthcare The Federal Tax Service Russian Ministry of Industry and Trade Ministry of Finance The Ministry of Communications and Mass Communications		

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* Optional position is appointed by the Board of the presidium

2. The content of the priority project

<table>
<tr><td>Objective of the project</td><td colspan="5">Protecting the public from counterfeit, substandard and counterfeit drugs and provide an unlimited range of customers (citizens) the possibility of verifying the legality of registered drugs which are in public circulation, carried out with the use of automated traffic monitoring system labeled drugs from the manufacturer to the end user, with coverage of 100% medicines to December 31, 2018</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Index</td><td rowspan="2">Type indicator</td><td rowspan="2">Baseline *</td><td colspan="3">Period year</td></tr>
<tr><td>2017**</td><td>2018</td><td>2025</td></tr>
<tr><td></td><td>Coverage of individual marking of registered drugs which are in public circulation, with the ability to check an unlimited range of consumers (citizens) of their legality</td><td>main</td><td>0</td><td>-</td><td>100%</td><td>100%</td></tr>
<tr><td colspan="6">* Base value of the index at the reporting date.
** As part of an experiment on a voluntary basis - at least 5 international nonproprietary names for drugs included in the list of drugs for the treatment of patients with hemophilia, cystic fibrosis, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissue, multiple sclerosis, persons after transplantation of organs and (or) tissues (hereinafter – “7 WNV”).</td></tr>
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Results of the project	1. Commissioning of "Federal Public information system for monitoring the movement of drugs from the manufacturer to the final consumer" (FGIS MDLP): - More than 350 thousand participants in the system – stakeholders handling drugs; - More than 5 billion packages of drugs monitored by the system annually. 2. Provided information services to an unlimited number of consumers (citizens) to verify the legality of drugs in circulation. 3. FGIS MDLP integrated with departmental information systems of key actors of the process of marking: - Uniform State Registry of Legal Entities - State Register of medicinal products, - Automated Systems "Sampling", "Licensing" - A system of interdepartmental cooperation, - Information systems of participants in the drug supply. 4. Using FGIS MDLP organized monitoring of expiration dates on drugs in circulation, withdrawal from circulation of substandard and counterfeit drugs and their destruction. 5. Carry out a campaign on television that promote the ability to check the legality of drugs, posted videos with social advertising, showing the ability to check the legality of drugs with the use of smartphones, tablets and devices placed in pharmacies. By advertising in the print media, published and distributed booklets and brochures.
Description of the results of the	1. Provide opportunities to all participants FGIS MDLP (hereinafter - the System) registration in the system LP movement operations at all stages of

project operation model	their treatment (the manufacturer, the organization of wholesale trade, including the importation of drugs, drugstores, medical organization, the implementation of the consumer). 2. Monitoring of drug movement at all stages of handling (the manufacturer, the organization of wholesale trade, including the importation of drugs, drugstores, medical organization, the implementation of the consumer) in the context of a particular drug, specific series drug, drug packaging. 3. Monitoring expiry dates of drugs in circulation. 4. Blocking the process of circulation of counterfeit, substandard and counterfeit drugs in respect of which the authorized federal executive body decided to suspend the treatment, or to be withdrawn from circulation and destroyed. 5. Monitoring retirement of counterfeit, substandard and counterfeit drugs and drug destruction process by comparing information on the drugs in circulation with information about blocked, withdrawn from circulation and destroyed drugs. Blocked withdrawn from circulation and destroyed drugs automatically output system of turnover and accounted for generating analytical reports. 6. Provide an opportunity for participants Systems produce analytical reports in the framework of their powers. 7. Holding the media shares, popularizing the opportunity for a wide range of consumers (citizens) check the legality of drugs in circulation. Placing clips with public service announcements on television and in print media, demonstrating the possibility of verifying the legality of drugs with the use of mobile devices as well as devices placed in pharmacies. The publication and distribution of booklets and brochures.

3. Stages and milestones

#	Name	Type (end stage / control point)	Date
1.	Initiated Project (Project Approved Passport)	Completion phase	October 25, 2016
2.	Signed decree of the Russian Government	Check Point	November 30, 2016
3.	Approved Master Plan	Completion phase	December 10, 2016
4.	Project documentation	Check Point	December 31, 2016
5.	Improved labeling system FTS of Russia	Check Point	March 31, 2017
6.	The system entered into pilot operation	Check Point	April 1, 2017
7.	Completed an experiment to control the marking (identification) marks and monitoring of medicines for medical use on a voluntary basis to a limited number of drugs from the list of 7VZN. The evaluation of the experimental results and the report to the Government. Approved budget for the	Completion phase	December 31, 2017

	second phase of the project. Started pilot operation systems		
8.	A campaign on television that promote the ability to check the legality of drugs	Check Point	January 1, 2018
9.	FGIS MDLP integrated with departmental information systems of key participants marking process	Check Point	January 1, 2018
10.	Coverage of 100% labeled medicines which are in public circulation	Check Point	December 31, 2018
11.	Implemented a project to introduce an automated system for monitoring the movement of drugs from the manufacturer to the end user to protect the public from counterfeit medicines and surgical removal from circulation of counterfeit and substandard drugs	Completion phase	January 15, 2018
12.	The project is completed (final report approved)	Completion phase	March 1, 2019

4. Budget Priority Project

Sources of financing		Year of realization			Total
		2017	2018	2019	
Budgetary sources, million rubles.	Federal	247,00**			247,00**
	Constituents of the Russian Federation				
	local				
Extra-budgetary sources, million rubles.					
TOTAL		247,00**			247,00**

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** Under the current budget financing of the Federal Tax Service

5. Description of the priority project

Communication with the Russian Federation state programs	- State program of the Russian Federation "Health Development" (Resolution of the Russian Government dated April 15, 2014 № 294); - The federal target program "Development of the Russian Federation, the pharmaceutical and medical industry for the period up to 2020 and beyond" (Government Resolution dated February 17, 2011 № 91); - Strategy of drug provision of the population of the Russian Federation for the period up to 2025 and its implementation plan (the order of the Russian Federation Ministry of Health on February 13, 2013 № 66).
Formal grounds for	Paragraph 5 of the Order of the President of the Russian Federation № Pr-285 of

initiating	20 February 2015 .: "The Ministry of Health of the Russian Federation to ensure the development and gradual implementation of an automated system for monitoring the movement of drugs from the manufacturer to the end consumer with labeling (codification) and identification of packages of medicines in to ensure effective monitoring of the quality of medicines in circulation and the fight against counterfeiting. "

Key risks and opportunities	Possible temporary reduction in the range of LP on certain trade names in connection with the need to validate the production line after the installation of the necessary equipment for marking.	Development plan and control equipment and means of telecommunications project participants.
	Increasing the cost of medicines, implemented using the system to a greater extent for the drugs low price segment.	Development of a financial model the impact of software and hardware equipment of the project participants on the cost of drugs. The use of the cheapest method of marking.
	The delay in obtaining drugs by the end user due to technical failures during the passage of medicines supply chain.	Minimization of technical failures due to overlap of the equipment and design of fault-tolerant system. Preparation of detailed process maps and training of employees at all stages of the supply chain.

Additional Information	The boundaries of the project. In the first stage (from 1 January 2017 until 31 December 2017) to hold on to the territory of the Russian Federation, an experiment to control the marking (identification) marks (hereinafter - the pilot) drugs for medical use on a voluntary basis to a limited number of drugs from the list of mostly 7VZN full commodity chain model from the manufacturer to the end user. In the second stage (from 1 January 2018 until 31 December 2018) the mandatory labeling of all 100% of medicines. The project is approved by the State commission on counteraction to illegal circulation of industrial products. The project is considered at a meeting of the Project Committee for the main direction of the strategic development of the Russian Federation "Health" October 24, 2016, adjusted timing of the project.